II. The Outstanding Rejections

Claims 1-7 stand rejected under 35 U.S.C. §112 (first paragraph) as failing to enable treatment of symptoms in an allergy patient.

Claims 8-14 stand rejected under 35 U.S.C. §112 (first paragraph) as failing to enable treatment of symptoms in an asthma patient.

Claims 15-20 stand rejected under 35 U.S.C. §112 (first paragraph) as failing to enable treatment of symptoms of otitis media.

Claims 15-20 stand rejected under 35 U.S.C. §112 (second paragraph) as being indefinite.

Claims 1-20 stand rejected under 35 U.S.C. §112 (second paragraph) as being indefinite.

Claims 8-14 stand rejected under 35 U.S.C. §102(e) as being anticipated by McMichael, U.S. Patent No. 6,100,244.

Claims 15-20 stand rejected under 35 U.S.C. §102(e) as being anticipated by McMichael, U.S. Patent No. 5,948,768.

Claims 1-7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over McMichael U.S. Patent No. 5,948,768 or McMichael U.S. Patent No. 5,726,160 in view of Kuby (Immunology, Kuby ed., page 360 (1992)).

Claims 8-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over McMichael U.S. Patent No. 5,948,768 or McMichael U.S. Patent No. 5,726,160 in view of Murray (The Textbook of Respiratory Medicine, (1988)).

Claims 1-7 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of McMichael U.S. Patent No.

5,948,768 or claims 1-7 of McMichael U.S. Patent No. 5,726,160 in view of Kuby (Immunology, Kuby ed., page 360 (1992)).

Claims 8-14 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of McMichael U.S. Patent No. 5,948,768 or claims 1-7 of McMichael U.S. Patent No. 5,726,160 in view of Murray (The Textbook of Respiratory Medicine, (1988)).

Claims 15-20 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of McMichael U.S. Patent No. 5,948,768.

III. Patentability Arguments

A. The Rejections of Claims 1-7 Under 35 U.S.C. §112 (First and Second Paragraphs) Should Be Withdrawn

The rejections of claims 1-7 under 35 U.S.C. §112 (first and second paragraphs) for indefiniteness and as failing to enable treatment of symptoms in an allergy patient should be withdrawn as the claims have now been amended to recite a step wherein a therapeutic effect is obtained. In addition, claim 1 has been amended to recite that the DNA is administered sublingually. While Applicants submit that their methods are useful to treat respiratory congestion and the symptoms of allergies by different modes of administration and point out that McMichael U.S. 5,955,442 is not limited to sublingual administration in the treatment of respiratory congestion, claim 1 has been amended to expedite allowance of the claims.

The Action raises issues relating to various statements in the specification. Clarification of those statements is set out herein. With respect to the question of what "preexposure" refers to in Example XXX, it refers to preexposure to allergen which was heavy

air in this case. In addition, each of Examples XXXI, XXXII and XXXIII are not prophetic but reflect work and results actually carried out. These examples support treatment of symptoms of allergies beyond respiratory congestion. (See the accompanying Declaration of John McMichael at paragraph 2.) Accordingly, the rejections of claims 1-7 under 35 U.S.C. §112 (first and second paragraphs) should be withdrawn.

B. The Rejections of Claims 8-14 Under 35 U.S.C. §112 (First and Second Paragraphs) Should Be Withdrawn

The rejections of claims 8-14 under 35 U.S.C. §112 (first and second paragraphs) as failing to enable treatment of symptoms in an asthma patient should be withdrawn as the claims have now been amended to recite a step wherein a therapeutic effect is obtained. In response to the rejection that the specification does not enable treatment of asthma symptoms not associated with overproduction of mucous, Applicants submit that their Examples XXXIV and XXXV related to subjects who suffered from constriction of airways characteristic of asthma with consequent negative impact on their ability to carry out activities of daily life. As discussed in the accompanying Declaration of John McMichael (paragraph 3), practice of the method of the invention was successful in alleviating the constriction of airways of those two subjects in a manner which allowed them to carry out the activities of daily life. Further, the treatment resolved the respiratory symptoms of the subjects in a manner which was unaccompanied by a productive cough.

In addition, the claims need not be limited to sublingual modes of administration because of the success in treating symptoms of equine Heaves which is a chronic obstructive pulmonary disorder (COPD) resulting from an allergic reaction to either mold spores in hay or pollen and not associated with excess mucous production. Vernon Durie V.M.D. reports in his accompanying Declaration that subcutaneous administration of the DNA containing

compositions of the invention to horses afflicted by Heaves alleviated symptoms of coughing, wheezing, and labored expiration from the lungs. Further, the accompanying Declaration of Harry C. Gurney D.V.M. reports successful treatment of Heaves in a horse as well as COPD in small animals including dogs, a cat, and a rabbit by subcutaneous administration of the DNA containing compositions of the invention.

Accordingly, claims 8-14 are fully enabled and the rejections of claims 8-14 under 35 U.S.C. §112 (first and second paragraphs) should be withdrawn.

C. The Rejection of Claims 15-20 Under 35 U.S.C. §112 (First and Second Paragraphs) Should Be Withdrawn

The rejections of claims 15-20 under 35 U.S.C. §112 (first and second paragraphs) for indefiniteness and for failing to enable treatment of symptoms in an otitis media patient should be withdrawn as the claims have now been amended to recite a step wherein a therapeutic effect is obtained. In response to the rejection that the specification does not enable treatment of all otitis media symptoms, Applicants have amended their claims to recite treatment of pain symptoms of otitis. In addition, to distinguish the present claims from those of issued U.S. Patent No. 5,948,768 which is directed to treatment of otitis media symptoms by sublingual administration of DNA, claim 15 has been amended to recite the step of administering eardrops of DNA to the ear. Accordingly, the rejections of claims 15-20 under 35 U.S.C. §112 (first and second paragraphs) should now be withdrawn.

D. The Rejection of Claims 8-14 Under 35 U.S.C. §102(b) Should Be Withdrawn

The rejection of claims 8-14 under 35 U.S.C. §102(b) over U.S. 6,100,244 ("the '244 Patent) should be withdrawn because the disclosure in the '244 Patent was derived from the sole inventor (McMichael) of the subject matter of claims 8-14 in the present application as set out in the accompanying Declaration. Moreover, the disclosure of treatment of dyspnea

symptoms of respiratory distress does not anticipate the treatment of symptoms of asthma as recited by claims 8-14 of the present application. For these reasons, the rejection of claims 8-14 under 35 U.S.C. §102(b) should be withdrawn.

E. The Rejection of Claims 15-20 Under 35 U.S.C. §102(b) Should Be Withdrawn

The rejection of claims 15-20 under 35 U.S.C. §102(b) over U.S. 5,948,768 ("the '768 Patent) should be withdrawn in light of the amendment of the present claims to more clearly recite that the administration of DNA is by eardrop to the ear. Moreover, the '768 Patent is not available as a reference against claims 15-20 of the present application because the disclosure of treatment of otitis media in the '768 Patent was derived from the inventors Michael and Allen of the subject matter of claims 15-20 as set out in the accompanying Declaration of John McMichael. Accordingly, the rejection of claims 15-20 under 35 U.S.C. §102(b) over U.S. 5,948,768 should be withdrawn.

F. The Rejection of Claims 1-7 Under 35 U.S.C. §103(a) Should Be Withdrawn

The rejection of claims 1-7 over the combination of McMichael 5,994,442 or McMichael U.S. 5,726,160 with Kuby should be withdrawn because there is no suggestion in the Michael patents that administration of DNA will treat the non-congestion symptoms of allergies as recited in the claims as amended. While allergy patients also have respiratory congestion, there is no teaching in the disclosures of the cited McMichael patents that suggests successful treatment of the non-congestion symptoms of allergies. For these reasons, the rejection of claims 1-7 should be withdrawn.

G. The Rejection of Claims 8-14 Under 35 U.S.C. §103(a) Should Be Withdrawn

The rejection of claims 8-14 over the combination of McMichael 5,994,442 or McMichael U.S. 5,726,160 with Murray should be withdrawn because there is no suggestion in the Michael patents that administration of DNA will treat the non-congestion symptoms of

asthma as recited in the claims as amended. While asthma patients can also have respiratory congestion, there is no teaching in the disclosures of the cited McMichael patents that suggests successful treatment of the non-congestion symptoms of asthma. For these reasons, the rejection of claims 8-14 should be withdrawn.

H. The Double Patenting Rejection of Claims 1-7 Should Be Withdrawn

The double patenting rejection of claims 1-7 over the combination of claims 1-6 of McMichael 5,994,442 or claims 1-7 of McMichael U.S. 5,726,160 with Kuby should be withdrawn because there is no suggestion in the Michael patents that administration of DNA will treat the non-congestion symptoms of allergies as recited in the claims as amended. While allergy patients also have respiratory congestion, there is no teaching in the disclosures of the cited McMichael patents that suggests successful treatment of the non-congestion symptoms of allergies. For these reasons, the obviousness-type double patenting rejection of claims 1-7 should be withdrawn.

I. The Double Patenting Rejection of Claims 8-14 Should Be Withdrawn

The double patenting rejection of claims 8-14 over the combination of claims 1-6 of McMichael 5,994,442 or claims 1-7 of McMichael U.S. 5,726,160 with Murray should be withdrawn because there is no suggestion in the Michael patents that administration of DNA will treat the non-congestion symptoms of asthma as recited in the claims as amended. While asthma patients also have respiratory congestion, there is no teaching in the disclosures of the cited McMichael patents that suggests successful treatment of the non-congestion symptoms of asthma. For these reasons, the obviousness-type double patenting rejection of claims 8-14 should be withdrawn.

CONCLUSION

For all of the foregoing reasons, the rejections should now be withdrawn and an early notice of all pending claims 1-20 is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, he is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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By: _____
Jeffrey S. Sharp
Reg. No. 31,879

April 18, 2001

VERSION WITH MARKING TO SHOW CHANGES MADE

1. [AMENDED] A method for treating allergy symptoms in a patient, comprising the step of:

administering in a manner so as not to effect gene transfer an effective amount of DNA in a pharmaceutically-acceptable vehicle to a patient having allergy symptoms such that the allergy symptoms not associated with respiratory congestion are reduced.

8. [AMENDED] A method for treating asthma symptoms not associated with respiratory congestion in a patient, comprising the steps of:

administering in a manner so as not to effect gene transfer a therapeutically effective amount of DNA in a pharmaceutically-acceptable vehicle to a patient having asthma symptoms such that the asthma symptoms not associated with respiratory congestion are reduced.

15. [AMENDED] A method for treating symptoms of otitis media, comprising the step of:

[topically] administering eardrops to the ear in a manner so as not to effect gene transfer an effective amount of DNA in a pharmaceutically-acceptable vehicle to a patient having otitis media such that pain symptoms associated with otitis media are reduced.